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| 10/049,497      | 02/13/2002  | Edel Bernadette O'Toole | CM2140              | 7650             |

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,497

Applicant(s)

O'TOOLE ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Receipt of preliminary amendment A dated 2-13-02 and IDS dated 8-29-02 is acknowledged.

Claims 1-10 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim states "tyrosine compound" is a C1-C4, which is indefinite because it is unclear where the C1-C4 does not completely define what the derivative is. It appears from the original claim 9 that applicants intend to claim tyrosine as a C1-C4 alkyl ester and the same is considered for examination.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 987,800 (GB) or DE 1,617,477 (DE).

GB discloses cosmetic composition containing amino acids tyrosine, histidine, lysine etc., for use as a hair cream, hair tonic, skin lotion etc (examples 1 –5).

DE discloses a hair tonic composition comprising amino acids such as histidine, tyrosine and tryptophan (example on page 6).

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Instant claims recite tyrosine compounds, histidine compounds, lysine compounds, all of which read on the amino acids of examples of GB and example of DE. However, neither reference explicitly states the solubility of the amino acids. However, the claimed solubility is inherent to the amino acids of GB and DE because according to Merck Index, lysine is freely soluble in water, Histidine has a solubility of 41.9 g/l, and the solubility of tyrosine and tryptophan is 0.147 g/l and 0.23 g/l at 0 degrees C respectively, and increases with temperature. Thus, DE and GB anticipate instant claims.

3. Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,201,235 to Ciavatta or US 5,053,230 to Gazzani.

Ciavatta disclose amino acid-vitamin formulations for skin, hair and scalp as conditioners. The composition of Ciavatta recites the claimed amino acids (col. 4, lines 1-36 and example 1 in cols. 7-8). Ciavatta disclose a method of treating scalp with the composition containing claimed amino acids (col. 7). The claimed solubility is inherent to the amino acids tryptophan, histidine, tyrosine and lysine taught by Ciavatta (see above explanation).

Gazzani discloses a cosmetic composition for promoting trophism of hair follicles comprising nutrient substances, including the claimed amino acids, histidine, tyrosine, tryptophan and lysine (example composition in col. 4, lines 1-29). Examples 4-6 recite hair lotions compositions. The claimed solubility is inherent to the amino acids tryptophan, histidine, tyrosine and lysine taught by Gazzani (see above explanation). Thus, Ciavatta and Gazzani anticipate instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of DE 1,617,477 (DE), GB 987,800 (GB), Gazzani or Ciavatta in view of US 5,290,562 to Meybeck et al (Meybeck).

The amino acid containing compositions of DE, GB, Ciavatta or Gazzani, all discussed above, do not teach alkyl ester of tyrosine, as claimed.

Meybeck teaches cosmetic compositions containing methyl tyrosinate, ethyl tyrosinate or stearyl tyrosinate for increasing the content of melanin and thus improve the hair complexion. Meybeck teaches that tyrosine being hydrophilic does not penetrate easily through the corneal layer and thus suggests using tyrosine esters such as methyl or ethyl tyrosinate and incorporated in liposomes (col. 2, lines 11-40 & lines 57-65). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to substitute tyrosine in the amino acid compositions of GB or DE or Ciavatta or Gazzani with ethyl or methyl tyrosinate with an expectation to increase the penetration of tyrosine across corneal layer, increase the melanin formation and thus increase the hair complexion.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,544,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compounds of the patent constitute a species of the generic amino acid compounds of the instant claims. The species of the patent anticipates the genus claimed in the instant, and a patent to the genus would necessarily extend the rights of the species should the genus issue as a patent after the species.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,500 to O'Toole (hereafter '500).

'500 teach hair care compositions comprising compounds that constitute the derivatives of amino acids (see col. 2). In particular, the compounds of '500 include ester derivatives of amino acids that include the claimed tryptophan, histidine, lysine, and tyrosine as well as other

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amino acids (col. 4). Instant description of amino acid derivatives and their structure read on the structure of the amino acid compounds of '500. '500 also describe the claimed solubility of amino acids (lines bridging cols. 5- 7). Instant claims recite only four amino acid compounds, whereas the formula I of '500 encompass derivatives of several other amino acids. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the ester derivatives of tyrosine, tryptophan, histidine and lysine from the compounds of '500 because the latter teaches that ester derivatives of amino acids reduce the problems of solubility and odor commonly seen in the hair compositions containing amino acids.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or

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subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

August 7, 2003